March 27, 2001

TO: FDA Commissioner
Docket No. 00N-1396/00D-1598 63 19 '01 APR -4 A10:21
FDA Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville,MD 20852

I am writing to express my strong opposition to FDA's new proposed rules and guidelines on genetically engineered (GE) foods. Voluntary labeling and notification requirements on companies and products involved with genetically engineered foods are completely inadequate to protect the health, safety and welfare of American consumers.

The doctrine of "substantial equlivalence" between genetically engineered foods and other foods, and its assumption that the risks are comparable, is not grounded in sound science. There is no scientific basis for this unsubstantiated assumption. On the contrary, FDA's own expert staff scientists, as well as many independent scientists, including molecular geneticists in the U.S. and throughout the world, have documented the potential and reality of qualitatively different risks from the process of producing genetically engineered food products. There is no precision to the gene transfer process, contrary to what you lead the public to believe, and you do not confront the fact of the random nature of the GE process, and the many possible consequences of this. The environment of the cell and DNA is poorly understood, but enough is known to clearly falsify the reductionist assumptions on which gene patenting and GE techniques and claims to precision are based. Numerous studies in the literature for the past twenty years document pleiotropic, positional and epigenetic feedback effects some of which have been shown to produce new toxic protein products and metabolic effects. They have documented gene instability, horizontal gene transfer, the persistence of DNA products in the human digestive system, and the potential for creation of new virulent viral diseases and new antibiotic-resistant bacteria from the cell culture techniques used, and the transfer vectors employed. The use of promoters which override the normal dynamic homeostasis in the cells can result in many unintended, perverse and pathological consequences, which have never been tested for or studied by your agency.

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For your agency to make its glib assurances about the safety of GE foods is nothing but lies to mislead the public. It is not only irresponsible, but criminal on your part to use American and other consumers as guinea pigs in uncontrolled experiments on a mass scale, which is what the premature commercial release of numerous untested, potentially toxic products into the marketplace amounts to. Extensive, longitudinal whole-body and molecular characterization studies of new as well as existing and known possible byproducts of GE products must be undertaken - on a case-by-case basis for each new product, and probably for each new batch of a product, since the assumption of uniformity is not borne out between GE cell cultures of the same transfer product - before you have any right to make "safety" claims or to let these GE food products on the market.

I fully support:

a) an immediate moratorium on continuation of allowing current GE food products in the marketplace and a moratorium on all new GE food and other products until long-term studies demonstrate unequivocally that they are safe for human health and for the environment. The precautionary principle should be the guiding directive. The burden of proof should be on the GE food companies and yourselves to prove safety before they are commercially permitted.

b) All GE foods should be subject to mandatory pre-market safety testing of an extensive and comprehensive nature, and which do not presuppose "substantial equiavlence" to comparable non-GE food products.

c) All GE foods, and individual food ingredients in the case of processed foods, should be clearly labeled so consumers can make an informed choice.

Very Truly Yours,

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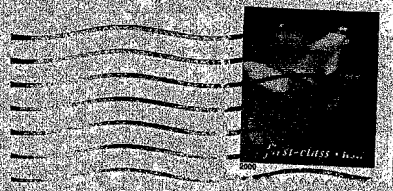

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